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9/25/92

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

5 In re Application of) Group Art Unit: 1205
GEORGE A. BROOKS)
Serial No. 07/471,287)
Filed: January 26, 1990)
10 For: METHOD AND COMPOSITION)
FOR NUTRITIONAL)
SUPPLEMENTATION DURING)
EXERCISE AND RECOVERY)

DECLARATION OF
GEORGE A. BROOKS
UNDER 37 C.F.R. § 1.132
2001 Ferry Building
San Francisco, CA 94111
(415) 433-4150

15 Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

20 I, George A. Brooks, do hereby declare and state
that:

25 1. I am the sole inventor in the above
referenced patent application. I have conducted
and/or supervised a considerable amount of scientific
research in the field of exercise physiology. My
curriculum vitae is attached as Exhibit A.

2. I have reviewed the Kober reference which
was cited against the claims in the above referenced
patent application. The below comments address the
teachings of this reference as compared to the
invention claimed in the instant application. My
below comments also provide a general discussion of
the conventional wisdom in the art concerning lactic
acid and its effects in exercise physiology.

3. The Kober patent is directed to a food
composition that is rich in minerals, and contains
lactate as a stabilizing agent. Depending on whether

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GROUP 1205

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CERTIFICATE OF MAILING

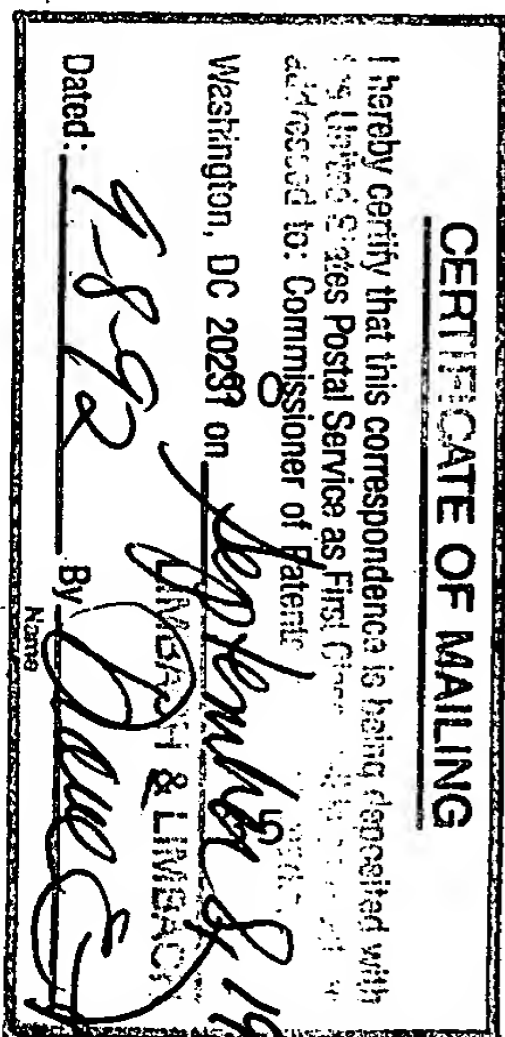
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one follows the wet formulation (lines 24-46) or dry formulation (lines 112-115) of Kober, the resulting solution will have a mineral salt concentration ranging from 11-20%. Such a salt concentration is far too high to benefit fluid, electrolyte or carbohydrate balance during exercise and/or recovery.

4. As provided in Table 12-2 from Eckert, Randall and Augustine, Animal Physiology Mechanisms and Adaptation, Third Edition (Exhibit B), sea water contains 460 and 540 mOsmole of sodium and chloride, respectively. Thus, at 540mM, the NaCl content of sea water would approximate 31 g/l or 3.1%. In effect, the consumption of Kober's mineral salt solution would be worse for the dehydrated athlete than consumption of sea water.

5. For comparison, human plasma concentration is approximately 304 mOsmol, of which 142 mOsmol is from sodium, and 104 mOsmol is from chloride. Because of the relatively high NaCl content of plasma, normal saline for intravenous infusion contains 155 mEq each of Na⁺ and Cl⁻, yielding a total NaCl content of 310 mEq (0.9g NaCl per 100ml water, or 0.9%).

6. Thus, Kober's solutions tend to be a full order of magnitude greater in salt concentration than normal saline solutions used for intravenous infusion. In contrast to plasma at 0.9%, the sodium content of sweat is quite small (18 mEq per liter, or 0.05%). The salinity of human plasma rises during exercise because fluids are lost while mineral salts remain in the plasma. For these reasons, salinity of fluid electrolyte replacement beverages typically reflect sweat losses, rather than plasma content. For

example, in the instant application, 0.2% sodium lactate is used to replenish sodium losses during exercise.

5 7. For many years, the conventional wisdom in
the art of exercise physiology was that muscle
fatigue was caused by accumulation of lactic acid.
Therefore, carbohydrate nutrient compositions having
either lactic acid or lactate salts as a nutritional
component were not considered beneficial to the
10 exercising athlete because it was believed that
additional lactates would accelerate fatigue.
Therefore, conventional thought on lactic acid taught
away from the use of lactates as a nutritional
supplement for exercising athletes. The relevant
15 portions of several textbook references, which date
from 1932 to 1986, attached hereto (Exhibit C)
demonstrate the conventional wisdom on lactic acid
fatigue.

20 8. More recently, beneficial metabolic effects
of lactate have been identified. An example of this
beneficial effect is reported in the textbook
reference attached as Exhibit D. However, even the
more recent scientific literature does not disclose
or suggest the concept of using lactic acid salts as
25 a carbohydrate nutritional supplemental. This
concept was not known prior to the instant invention.

30 9. I further declare, under penalty of perjury
under the laws of the United States of America, that
all statements made herein of my own knowledge are
true and that these statements were made with the
knowledge that willful false statements and the like
are punishable by fine or imprisonment, or both,

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under Section 1001 of Title 18 of the United States
Code.

Dated: 9/4/92

George A. Brooks
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